



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Vladimir SABETSKY  
Title: ORAL INSULIN COMPOSITION  
AND METHODS OF MAKING  
AND USING THEREOF  
Appl. No.: 10/792,376  
Filing Date: 03/04/2004  
Examiner: Unassigned  
Art Unit: Unassigned

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Commissioner for Patents  
PO Box 1450  
Alexandria, Virginia 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicant in order to comply with Applicant's duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document, except as noted below, is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The USPTO has waived the requirement under 37 CFR 1.98(a)(2)(i) to submit copies of U.S. patents and U.S. patent application publications when citing and submitting an Information Disclosure Statements in a patent application filed after June 30, 2003 and in an international application that has entered the national stage under 37 USC §371 after June 30, 2003. Accordingly, copies of these types of documents are not being supplied in connection with this application. Reference is being made to Pre-OG Notice from Office of Patent Legal Administration dated July 25, 2003, *Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003.*

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicant does not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), within three (3) months of the filing date of the application.

**RELEVANCE OF EACH DOCUMENT**

All of the documents are in English.

Applicant respectfully requests that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

Respectfully submitted,

Date 4/21/04

By Leon Radomsky

FOLEY & LARDNER LLP  
Customer Number: 22428  
Telephone: (202) 672-5300  
Facsimile: (202) 672-5399

Leon Radomsky  
Attorney for Applicant  
Registration No. 43,445

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

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Substitute for form 1449B/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> Date Submitted: 4/21/04 <span style="float: right;">APR 21 2004</span> (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/792,376
				Filing Date	3/4/04
				First Named Inventor	Vladimir SABETSKY
				Group Art Unit	Unassigned
				Examiner Name	Unassigned
				Attorney Docket Number	028093-0113
Sheet	1	of	3		

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	A1	2002/0054914		Morcol, Tulin et al	5/9/02	
	A2	6,482,413	B1	Chalasani, et al	11/19/02	
	A3	6,395,302	B1	Hennink et al	5/28/02	
	A4	6,303,148	B1	Hennink et al	10/16/01	
	A5	4,713,249		Schroder	12/15/87	
	A6	6,264,943	B1	Cherksey	7/24/01	
	A7	Re 37,950	E	Dunn et al	12/31/02	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	A8	EP	1 184 032	A1	OctoPlus B.V.	3/6/02		Y
	A9	WO	02/17884	A1	Octoplus B.V.	3/7/02		Y
	A10	WO	03/024425	A1	McGurk	3/27/03		Y
	A11	WO	98/14174		Vivorx Pharm Inc	4/9/98		Y
	A12	WO	01/01964	A2	Sedum Laboratories Inc.	1/11/01		Y
	A13	WO	84/00294		Schroder, Ulf	2/2/84		Y

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	A14	Griffith L. Acta Mater. 48 (2000): 263-277	Y
	A15	Angelova N. and Hunkeler D., TIBTECH, 17 (1999): 409-421	Y
	A16	Tirrell M., Kokkoli E., Biesalski M., Surface Science 500 (2002): 61-83	Y
	A17	Madsen S., Moony D., PSTT 11 (2000): 381-384	Y

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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		<b>First Named Inventor</b>	Vladimir SABETSKY
		<b>Group Art Unit</b>	Unassigned
		<b>Examiner Name</b>	Unassigned
Date Submitted: 4/21/04		<b>Attorney Docket Number</b>	028093-0113
(use as many sheets as necessary)			
Sheet	2	of	3

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Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	A18	Eliaz R., Szoka F., Gene Therapy 9 (2002): 1230-1237	Y
	A19	Blain J.F., Maghni K., Pelletier S. and Sirois P. Inflamm. Res. 48 (1999): 386-392	Y
	A20	Crystallized carbohydrate spheres as a slow release matrix for biologically active substances, Ulf Schroder, Biomaterials 1984, Vol. 5 March	Y
	A21	Crystallized Carbohydrate Spheres for Slow Release and Targeting, Ulf Schroder, Methods in Enzymology, Vol. 12	Y
	A22	Surfactant-Free Preparation of Biodegradable Hydrogel Microspheres for Protein Release, Yasuhiko Tabata, et al., Journal of Bioactive and Compatible Polymers, Vol. 14-September 1999	Y
	A23	Partitioning in Aqueous Two-Phase Systems. A comprehensive bibliography in three parts: (1956-1984; 1985-1990; 1991-present) Part III: 1991-present Part II: 1985-1990	Y
	A24	Local and distant transfection of mdx muscle fibers with dystrophin and LacZ genes delivered in vivo by synthetic microspheres, A. Baranov, et al., Gene Therapy 6 (1999), 1406-1414	Y
	A25	Regulated insulin release from biodegradable dextran hydrogels containing poly(ethylene glycol), Kazuteru Moriyama, et al., Journal of Controlled Release 42 (1996) 237-248	Y
	A26	Lantus Prescribing Information – Aventis Pharmaceuticals ( <a href="http://www.aventis-us.com/PIs/lantus_TXT.html">http://www.aventis-us.com/PIs/lantus_TXT.html</a> visited 2/23/04)	Y
	A27	Sephadex-based cell-affinity adsorbents: preparation and performance, Geert Besselink, et al, Biotechnol., Appl. Biochem. 35 (2002), 55-60	Y
	A28	Formation of dextran hydrogels by crystallization, R.J.H. Stenekes, et al., Biomaterials 22 (2001) 1891-0898	Y
	A29	Enhanced Loading and Activity Retention of Proteins in Hydrogel Delivery Systems, S.H. Gehrke, et al, Proceed. Intern. Symp. Control. Rel. Bioact. Mater., 22 (1995), Controlled Release Society, Inc., p. 145-146	Y
	A30	Amidon GL, Lee HJ, Absorption of Peptide and Peptidomimetic Drugs, Ann. Rev. Pharmacol. Toxicol 1994; 34: 321-41	Y
	A31	Abstract, Pharmacological Management of Type 2 Diabetes Mellitus: rationale for rational use of insulin., Mayo Clin Proc. 2003 Apr; 78(4): 459-67, Chan JL, Abrahamson MJ, Mayo Clin Proc. 2003 Apr;78(4):411-3	A

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	A32	Abstract, Improvement of Transmucosal Absorption of Biologically Active Peptide Drugs, Akira Yamamoto, Department of Biopharmaceuticals, Kyoto Pharmaceutical University, Misasagi 8/31/2001	A
	A33	Abstract, 2002 American Diabetes Association Annual Meeting, Significant Hypoglycemic Effect of a Perorally-delivered Insulin in the Treatment of Streptozocin-induced Diabetic Rats, Frank K. Leung, Jiang Li, Lanqui Huang and Emily Leung.	A
	A34	Abstract, Oligopeptides as Potential Insulin Drug Delivery System, Raphael M. Ottenbrite, Rui Zhao, Mamoru Haratake, Dept. of Chemistry, Virginia Commonwealth University, Richmond, VA	A
	A35	Abstract, Insulin loaded multilayer dextran sulfate/protamine microparticles Nadezda G. Balabushevich <sup>1</sup> , Gleb B. Sukhorukov <sup>2</sup> and Natalia I. Larionova <sup>1</sup> , 1 Department of Chemistry, Moscow State University, 119992 Russia, 2 Max-Planck Institute of Colloids and Interfaces, Golm/Potsdam, 14424, German.	A
	A36	Abstract, Insulin Containing Polyethyleneimine-dextran Sulfate Nanoparticles, Int J. Pharm. 2003 Apr 14; 255(1-2):139-51, Tiyaboonthai W., Woiszwillo J., Sims RC, Middaugh CR, Dept. of Pharmaceutical Chemistry, School of Pharmacy, The University of Kansas, 2095 Constant Ave., Lawrence, KS 66047-3729 USA	A
	A37	Abstract, Microfabricated porous silicon particles enhance paracellular delivery of insulin across intestinal Caco-2 cell monolayers, Pharm Res. 2003 Jan; 20(1):110-6., Forasker AB, Walczak RJ, Cohen MH, Boiarski TA, Grove CF, Swaan PW, The Ohio State University of Pharmacy, Division of Pharmaceutics, 500 West 12 <sup>th</sup> Ave., Columbus, OH 43210, USA	A
	A38	Abstract, Gastrointestinal absorption enhancement of insulin by administration of enteric microspheres and SNAC to rats, J. Microencapsul. 2004 Jan-Feb; 21(1): 37-45, Qi R, Ping QN	A
	A39	Abstract, Preparation and characterization of enteric microspheres containing bovine insulin by a w/o/w emulsion solvent evaporation method, Chem Pharm Bull (Tokyo) 1998 Oct; 46(10): 1613-7, Nagareya N., Uchida T, Matsuyama K.	A
	A40	Abstract, Intestinal absorption of human insulin in pigs using delivery systems based on superporous hydrogel polymers, Int J. Pharm. 2002 Oct 24; 247(1-2): 57-66, Dorkoosh FA, Verhoef JC, Borchard G, Rafiee-Tehrani M, Verheijden JH, Junginger HE	A
	A41	Abstract, Peroral delivery systems based on superporous hydrogel polymers: release characteristics for the peptide drugs buserelin, octreotide and insulin, Eur J Pharma Sci. 2002 Jun; 15(5): 433-9, Dorkoosh FA, Coos Verhoef J, Ambagts MH, Rafiee-Tehrani M, Borchard G, Junginger HE	A
	A42	Abstract, Development and characterization of a novel peroral peptide drug delivery system. J Control Release. 2001 Apr 28; 71(3): 307-18, Dorkoosh FA, Verhoef JC, Borchard G, Rafiee-Tehrani M, Junginger HE	A

Examiner Signature		Date Considered	
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**PROPRIETARY MATERIAL NOT OPEN TO PUBLIC.  
TO BE OPENED ONLY BY EXAMINER OR OTHER AUTHORIZED  
PATENT AND TRADEMARK OFFICE EMPLOYEE**

***IN THE UNITED STATES PATENT AND TRADEMARK OFFICE***

Applicant: Vladimir SABETSKY  
Title: ORAL INSULIN COMPOSITION  
AND METHODS OF MAKING  
AND USING THEREOF  
Appl. No.: 10/792,376  
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Art Unit: Unassigned

**PROPRIETARY INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR 1.56 AND MPEP §§ 724**

Commissioner for Patents  
P.O. 1450  
Alexandria, Virginia 22313-1450

Sir:

The following is a copending U.S. patent application which relates to the above-identified application.

<u>Attorney Docket No.</u>	<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor</u>
028093-0114	10/792,383	3/4/04	Vladimir Sabetsky

Applicant considers the aforementioned document and the disclosure of their existence as pending application to constitute proprietary information. Accompanying this Proprietary Information Disclosure Statement is a transmittal letter indicating that the materials contained herein are proprietary, as required by MPEP § 724.02.

Applicant respectfully requests that the Examiner consider the foregoing information and provide in the next official communication the information set forth in MPEP § 724.04(a), particularly the information under item (D), so that the applicant can, if appropriate, subsequently file a petition to expunge those materials, as provided according to MPEP § 724.05.

Respectfully submitted,

Date

9/21/04

By



FOLEY & LARDNER LLP

Customer Number: 22428

Telephone: (202) 672-5300

Facsimile: (202) 672-5399

Leon Radomsky  
Attorney for Applicant  
Registration No. 43,445

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**TRANSMITTAL LETTER FOR  
PROPRIETARY INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. § 1.56 and M.P.E.P. §§ 724 and 724.02**

Commissioner for Patents  
P.O. 1450  
Alexandria, Virginia 22313-1450

Sir:

Attached hereto is a Proprietary Information Disclosure Statement submitting proprietary information to the Patent and Trademark Office in accordance with the requirements of 37 C.F.R. § 1.56 and MPEP § 724. Applicants respectfully request that the



information be considered only by the Examiner in charge of the above-caption application,  
or other authorized Patent and Trademark Office employee.

Respectfully submitted,

Date 4/21/04

By Leon Radomsky

FOLEY & LARDNER LLP

Customer Number: 22428

Telephone: (202) 672-5300

Facsimile: (202) 672-5399

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Attorney for Applicant  
Registration No. 43,445